

IN THE UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF NEW YORK

-----X  
CLYDE OWEN,

Plaintiff,

Index No.:  
07 CV 7424

-against-

**ANSWER**

BRISTOL-MYERS SQUIBB COMPANY, and  
SCHERING CORPORATION,

Defendants.  
-----X

Defendant Schering Corporation ("SCHERING") by and through its attorneys, SEDGWICK, DETERT, MORAN & ARNOLD LLP, as and for its ANSWER to Plaintiff's Complaint, states and alleges upon information and belief as follows:

**AS AND FOR AN ANSWER TO THE NATURE OF THE ACTION**

FIRST: The allegations of paragraph 1 are denied.

SECOND: The allegations of paragraph 2 are denied.

THIRD: SCHERING denies the allegations of paragraph 3, and specifically denies said paragraph in the form alleged in so far as SCHERING did not have any responsibility for marketing Tequin® after 2002.

FOURTH: SCHERING denies the allegations of paragraph 4, and specifically denies said paragraph in the form alleged in so far as SCHERING did not have any responsibility for marketing Tequin® after 2002.

FIFTH: The allegations of paragraph 5 are denied.

SIXTH: SCHERING denies the allegations of paragraph 6, and specifically denies said paragraph in the form alleged in so far as SCHERING did not have any responsibility for marketing Tequin® after 2002.

**AS AND FOR AN ANSWER TO PARTIES**

SEVENTH: It is admitted that the allegations of paragraph 7 are sufficient to bring this matter within the jurisdiction of this court except SCHERING is without knowledge or information sufficient to form a belief as to the truth of the allegations concerning plaintiff's alleged residence and administration of Tequin®. The remaining allegations of paragraph 7 are denied.

EIGHTH: The allegations of paragraph 8 are denied for lack of sufficient information to justify a belief.

NINTH: The allegations of paragraph 9 are denied except that SCHERING admits that it is a New Jersey corporation, that it marketed Tequin® (Gatifloxacin) in the United States in accordance with its Food and Drug Administration approved labeling, and that Tequin® (Gatifloxacin) is an antibacterial agent.

**AS AND FOR AN ANSWER TO GENERAL ALLEGATIONS**

TENTH: The allegations of paragraph 10 are denied.

ELEVENTH: The allegations of paragraph 11 are denied to the extent that plaintiff contends that SCHERING is responsible for any alleged injuries experienced by

plaintiff, and are denied for lack of sufficient information to justify a belief therein concerning plaintiff's alleged medical treatment. Defendant respectfully refers to the medical records and pharmacy records for plaintiff as to the circumstances surrounding the medical care and treatment rendered and plaintiff's alleged use of the product.

TWELFTH: The allegations of paragraph 12 are denied as to SCHERING.

THIRTEENTH: The allegations of paragraph 13 are denied as to SCHERING.

FOURTEENTH: The allegations of paragraph 14 are denied as alleged.

FIFTEENTH: The allegations of paragraph 15 are denied.

SIXTEENTH: Answering paragraph 16 of plaintiff's complaint, SCHERING admits that the Food and Drug Administration first approved the New Drug Application for Tequin® (Gatifloxacin) on December 17, 1999, and that Tequin® (Gatifloxacin) was thereafter marketed for various uses in accordance with its Food and Drug Administration approved labeling in the State of Arkansas and elsewhere.

SEVENTEENTH: The allegations of paragraph 17 are denied as alleged and SCHERING refers to the Food and Drug Administration approved Tequin® labeling for information concerning approved product indications.

EIGHTEENTH: The allegations of paragraph 18 are denied.

NINETEENTH: The allegations of paragraph 19 are denied except that SCHERING is without knowledge sufficient to form a belief as to the truth of the allegations concerning other defendants.

TWENTIETH: The allegations of paragraph 20 are denied except that SCHERING is without knowledge sufficient to form a belief as to the truth of the allegations concerning other defendants.

TWENTY-FIRST: SCHERING denies the allegations of paragraph 21, and specifically denies said paragraph in the form alleged in so far as SCHERING did not have any responsibility for marketing Tequin® after 2002.

TWENTY-SECOND: SCHERING denies the allegations of paragraph 22, and specifically denies said paragraph in the form alleged in so far as SCHERING had no responsibility for marketing Tequin® in Japan and did not have responsibility for marketing Tequin® in the United States after 2002.

TWENTY-THIRD: The allegations of paragraph 23 are denied except that SCHERING is without knowledge sufficient to form a belief as to the truth of the allegations concerning other defendants.

TWENTY-FOURTH: The allegations contained in paragraph 24 are unrelated to SCHERING and no response is required. To the extent that a response is required, the allegations are denied.

TWENTY-FIFTH: SCHERING denies the allegations of paragraph 25, and specifically denies said paragraph in the form alleged in so far as SCHERING did not have any responsibility for marketing Tequin® after 2002.

TWENTY-SIXTH: The allegations contained in paragraph 26 are unrelated to SCHERING and no response is required. To the extent that an answer is required, the allegations are denied.

TWENTY-SEVENTH: SCHERING denies the allegations of paragraph 27, and specifically denies said paragraph in the form alleged in so far as SCHERING did not have any responsibility for marketing Tequin® after 2002.

TWENTY-EIGHTH: SCHERING denies the allegations of paragraph 28, and specifically denies said paragraph in the form alleged in so far as SCHERING did not have any responsibility for marketing Tequin® after 2002.

TWENTY-NINTH: The allegations of paragraph 29 are denied. SCHERING further states that it complied with all relevant Food and Drug Administration regulations in the marketing of Tequin® (Gatifloxacin) consistent with its Food and Drug Administration approved labeling, and that SCHERING did not have any responsibility for marketing Tequin® after 2002.

THIRTIETH: The allegations contained in paragraph 30 are unrelated to SCHERING and no response is required. To the extent that an answer is required, the allegations are denied.

THIRTY-FIRST: The allegations of paragraph 31 are denied.

THIRTY-SECOND: The allegations of paragraph 32 are denied for lack of sufficient information to justify a belief therein. Defendant respectfully refers to the medical records and pharmacy records for plaintiff as to the circumstances surrounding the medical care and treatment rendered and plaintiff's alleged use of the product.

THIRTY-THIRD: The allegations of paragraph 33 are denied to the extent that plaintiff contends that SCHERING is responsible for any alleged injury experienced by the plaintiff, and denied for lack of sufficient information to justify a belief concerning plaintiff's medical treatment. Defendant respectfully refers to the medical records and pharmacy records for plaintiff as to the circumstances surrounding the medical care and treatment rendered and plaintiff's alleged use of the product.

THIRTY-FOURTH: The allegations of paragraph 34 are denied for lack of sufficient information to justify a belief therein. Defendant respectfully refers to the medical records and pharmacy records for plaintiff as to the circumstances surrounding the medical care and treatment rendered and plaintiff's alleged use of the product.

THIRTY-FIFTH: The allegations of paragraph 35 are denied for lack of sufficient information to justify a belief therein. Defendant respectfully refers to the medical records and pharmacy records for plaintiff as to the circumstances surrounding the medical care and treatment rendered and plaintiff's alleged use of the product.

THIRTY-SIXTH: The allegations of paragraph 36 are denied.

THIRTY-SEVENTH: The allegations of paragraph 37 are denied to the extent that plaintiff contends that SCHERING is responsible for any alleged damages sustained by the plaintiff.

THIRTY-EIGHTH: The allegations of paragraph 38 are denied.

THIRTY-NINTH: The allegations of paragraph 39 are denied.

**AS AND FOR AN ANSWER TO COUNT I  
STRICT LIABILITY IN VIOLATION OF ARKANSAS CODE § 16-116-101, et seq.**

FORTIETH: Answering the allegations of paragraphs 1 through 39, defendant repeats and incorporates by reference its responses to all preceding paragraphs of this answer as if fully set forth at length herein.

FORTY-FIRST: The allegations of paragraph 41 are denied.

FORTY-SECOND: The allegations of paragraph 42 are denied.

FORTY-THIRD: The allegations of paragraph 43 are denied for lack of sufficient information to justify a belief therein. Defendant respectfully refers to the medical records and pharmacy records for plaintiff as to the circumstances surrounding the medical care and treatment rendered and plaintiff's alleged use of the product.

FORTY-FOURTH: The allegations of paragraph 44 are denied.

FORTY-FIFTH: The allegations of paragraph 45 are denied.

FORTY-SIXTH: The allegations of paragraph 46 are denied in the form alleged. SCHERING further states that it complied with all relevant Food and Drug Administration regulations in the marketing of Tequin® (Gatifloxacin) consistent with its Food and Drug Administration approved labeling, and that SCHERING did not have any responsibility for marketing Tequin® after 2002.

FORTY-SEVENTH: The allegations of paragraph 47 are denied in the form alleged. SCHERING further states that it complied with all relevant Food and Drug Administration regulations in the marketing of Tequin® (Gatifloxacin) consistent with its Food and Drug

Administration approved labeling, and that SCHERING did not have any responsibility for marketing Tequin® after 2002.

FORTY-EIGHTH: The allegations of paragraph 48 are denied.

FORTY-NINTH: The allegations of paragraph 49 are denied in the form alleged. SCHERING further states that it complied with all relevant Food and Drug Administration regulations in the marketing of Tequin® (Gatifloxacin) consistent with its Food and Drug Administration approved labeling, and that SCHERING did not have any responsibility for marketing Tequin® after 2002.

FIFTIETH: The allegations contained in paragraph 50 are unrelated to SCHERING and no response is required. To the extent that an answer is required, the allegations are denied.

FIFTY-FIRST: The allegations of paragraph 51 are denied.

FIFTY-SECOND: The allegations of paragraph 52 are denied.

FIFTY-THIRD: The allegations of paragraph 53 are denied.

FIFTY-FOURTH: The allegations and all subparts of paragraph 54 are denied.

FIFTY-FIFTH: The allegations of paragraph 55 are denied.

FIFTY-SIXTH: SCHERING makes no response to the allegations contained in paragraph 56 of plaintiff's Complaint which are purely of a legal nature and refers all issues of law to the Court. To the extent an answer is required, the allegations of paragraph 56 are denied as alleged, except SCHERING admits that all parties request a jury trial.



**AS AND FOR AN ANSWER TO COUNT II**  
**NEGLIGENCE**

FIFTY-SEVENTH: Answering the allegations of paragraphs 1 through 56, defendant repeats and incorporates by reference its responses to all preceding paragraphs of this answer as if fully set forth at length herein.

FIFTY-EIGHTH: The allegations of paragraph 58 are denied.

FIFTY-NINTH: The allegations of paragraph 59 are denied.

SIXTIETH: The allegations of paragraph 60 are denied in the form alleged. SCHERING further states that it complied with all relevant Food and Drug Administration regulations in the marketing of Tequin® (Gatifloxacin) consistent with its Food and Drug Administration approved labeling, and that SCHERING did not have any responsibility for marketing Tequin® after 2002.

SIXTY-FIRST: The allegations and all subparts of paragraph 61 are denied.

SIXTY-SECOND: The allegations of paragraph 62 are denied as to SCHERING.

SIXTY-THIRD: The allegations of paragraph 63 are denied.

SIXTY-FOURTH: SCHERING makes no response to the allegations contained in paragraph 64 of plaintiff's Complaint which are purely of a legal nature and refers all issues of law to the Court. To the extent an answer is required, the allegations of paragraph 64 are denied as alleged, except SCHERING admits that all parties request a jury trial.

**AS AND FOR AN ANSWER TO COUNT III  
BREACH OF IMPLIED WARRANTY OF FITNESS**

SIXTY-FIFTH: Answering the allegations of paragraphs 1 through 64, defendant repeats and incorporates by reference its responses to all preceding paragraphs of this answer as if fully set forth at length herein.

SIXTY-SIXTH: The allegations of paragraph 66 are denied.

SIXTY-SEVENTH: The allegations of paragraph 67 are denied.

SIXTY-EIGHTH: The allegations of paragraph 68 are denied.

SIXTY-NINTH: The allegations of paragraph 69 are denied.

SEVENTIETH: The allegations of paragraph 70 are denied.

SEVENTY-FIRST: The allegations of paragraph 71 are denied.

SEVENTY-SECOND: The allegations of paragraph 72 are denied.

SEVENTY-THIRD: SCHERING makes no response to the allegations contained in paragraph 73 of plaintiff's Complaint which are purely of a legal nature and refers all issues of law to the Court. To the extent an answer is required, the allegations of paragraph 73 are denied as alleged, except SCHERING admits that all parties request a jury trial.

**AS AND FOR A N ANSWER TO COUNT IV  
BREACH OF IMPLIED WARRANTY OF MERCHANTABILITY**

SEVENTY-FOURTH: Answering the allegations of paragraphs 1 through 73, defendant repeats and incorporates by reference its responses to all preceding paragraphs of this answer as if fully set forth at length herein.

SEVENTY-FIFTH: The allegations of paragraph 75 are denied.

SEVENTY-SIXTH: The allegations of paragraph 76 are denied.

SEVENTY-SEVENTH: The allegations of paragraph 77 are denied.

SEVENTY-EIGHTH: The allegations of paragraph 78 are denied.

SEVENTY-NINTH: The allegations of paragraph 79 are denied.

EIGHTIETH: The allegations of paragraph 80 are denied.

EIGHTY-FIRST: The allegations of paragraph 81 are denied.

EIGHTY-SECOND: The allegations of paragraph 82 are denied.

EIGHTY-THIRD: The allegations of paragraph 83 are denied.

EIGHTY-FOURTH: The allegations of paragraph 84 are denied.

EIGHTY-FIFTH: The allegations of paragraph 85 are denied.

EIGHTY-SIXTH: The allegations of paragraph 86 are denied.

EIGHTY-SEVENTH: SCHERING makes no response to the allegations contained in paragraph 87 of plaintiff's Complaint which are purely of a legal nature and refers all issues of law to the Court. To the extent an answer is required, the allegations of paragraph 87 are denied as alleged, except SCHERING admits that all parties request a jury trial.

**AS AND FOR AN ANSWER TO COUNT V  
FRAUDULENT MISREPRESENTATION**

EIGHTY-EIGHTH: Answering the allegations of paragraphs 1 through 87, defendant repeats and incorporates by reference its responses to all preceding paragraphs of this answer as if fully set forth at length herein.

EIGHTY-NINTH: The allegations of paragraph 89 are denied.

NINETIETH: The allegations of paragraph 90 are denied.

NINETY-FIRST: The allegations of paragraph 91 are denied.

NINETY-SECOND: The allegations of paragraph 92 are denied.

NINETY-THIRD: The allegations of paragraph 93 are denied.

NINETY-FOURTH: The allegations of paragraph 94 are denied.

NINETY-FIFTH: The allegations of paragraph 95 are denied.

NINETY-SIXTH: The allegations of paragraph 96 are denied.

NINETY-SEVENTH: The allegations and all subparts of paragraph 97 are denied.

NINETY-EIGHTH: The allegations of paragraph 98 are denied.

NINETY-NINTH: The allegations of paragraph 99 are denied.

ONE HUNDREDTH: The allegations of paragraph 100 are denied.

ONE HUNDRED FIRST: The allegations of paragraph 101 are denied.

ONE HUNDRED SECOND: The allegations of paragraph 102 are denied.

ONE HUNDRED THIRD: The allegations of paragraph 103 are denied.

ONE HUNDRED FOURTH: The allegations of paragraph 104 are denied.

ONE HUNDRED FIFTH: The allegations of paragraph 105 are denied.

ONE HUNDRED SIXTH: SCHERING makes no response to the allegations contained in paragraph 106 of plaintiff's Complaint which are purely of a legal nature and refers all issues of law to the Court. To the extent an answer is required, the allegations of paragraph 106 are denied as alleged, except SCHERING admits that all parties request a jury trial.

**AS AND FOR AN ANSWER TO COUNT VI  
FRAUDULENT CONCEALMENT**

ONE HUNDRED SEVENTH: Answering the allegations of paragraphs 1 through 106, defendant repeats and incorporates by reference its responses to all preceding paragraphs of this answer as if fully set forth at length herein.

ONE HUNDRED EIGHTH: The allegations of paragraph 108 are denied

ONE HUNDRED NINTH: The allegations and all subparts of paragraph 109 are denied.

ONE HUNDRED TENTH: The allegations of paragraph 110 are denied.

ONE HUNDRED ELEVENTH: The allegations of paragraph 111 are denied.

ONE HUNDRED TWELFTH: The allegations of paragraph 112 are denied.

ONE HUNDRED THIRTEENTH: The allegations of paragraph 113 are denied.

ONE HUNDRED FOURTEENTH: The allegations of paragraph 114 are denied.

ONE HUNDRED FIFTEENTH: The allegations of paragraph 115 are denied.

ONE HUNDRED SIXTEENTH: The allegations of paragraph 116 are denied.

ONE HUNDRED SEVENTEENTH: The allegations of paragraph 117 are denied.

ONE HUNDRED EIGHTEENTH: SCHERING makes no response to the allegations contained in paragraph 118 of plaintiff's Complaint which are purely of a legal nature and refers all issues of law to the Court. To the extent an answer is required, the allegations of paragraph 118 are denied as alleged, except SCHERING admits that all parties request a jury trial.

**AS AND FOR AN ANSWER TO COUNT VII  
INTENTIONAL INFLICTION OF EMOTIONAL DISTRESS**

ONE HUNDRED NINETEENTH: Answering the allegations of paragraphs 1-118, defendant repeats and incorporates by reference its responses to all preceding paragraphs of this answer as if fully set forth at length herein.

ONE HUNDRED TWENTIETH: The allegations and all subparts of paragraph 120 are denied.

ONE HUNDRED TWENTY-FIRST: The allegations of paragraph 121 are denied.

ONE HUNDRED TWENTY-SECOND: The allegations of paragraph 122 are denied.

ONE HUNDRED TWENTY-THIRD: The allegations of paragraph 123 are denied.

ONE HUNDRED TWENTY-FOURTH: The allegations of paragraph 124 are denied.

ONE HUNDRED TWENTY-FIFTH: SCHERING makes no response to the allegations contained in paragraph 125 of plaintiff's Complaint which are purely of a legal nature and refers all issues of law to the Court. To the extent an answer is required, the allegations of paragraph 125 are denied as alleged, except SCHERING admits that all parties request a jury trial.

**AS AND FOR AN ANSWER TO COUNT VIII  
VIOLATION OF ARKANSAS CONSUMER PROTECTION ACT DECEPTIVE  
TRADE PRACTICES**

ONE HUNDRED TWENTY-SIXTH: Answering the allegations of paragraphs 1-125, defendant repeats and incorporates by reference its responses to all preceding paragraphs of this answer as if fully set forth at length herein.

ONE HUNDRED TWENTY-SEVENTH: The allegations of paragraph 127 are denied.

ONE HUNDRED TWENTY-EIGHTH: The allegations and all subparts of paragraph 128 are denied.

ONE HUNDRED TWENTY-NINTH: The allegations of paragraph 129 are denied.

ONE HUNDRED THIRTIETH: The allegations of paragraph 130 are denied.

ONE HUNDRED THIRTY-FIRST: SCHERING makes no response to the allegations contained in paragraph 131 of plaintiff's Complaint which are purely of a legal nature and refers all issues of law to the Court. To the extent an answer is required, the allegations of paragraph 131 are denied as alleged, except SCHERING admits that all parties request a jury trial.

**AS AND FOR AN ANSWER TO COUNT IX  
PUNITIVE DAMAGES**

ONE HUNDRED THIRTY-SECOND: Answering the allegations of paragraphs 1-131, defendant repeats and incorporates by reference its responses to all preceding paragraphs of this answer as if fully set forth at length herein.

ONE HUNDRED THIRTY-THIRD: The allegations and all subparts of paragraph 133 are denied.

ONE HUNDRED THIRTY-FOURTH: The allegations of paragraph 134 are denied.

ONE HUNDRED THIRTY-FIFTH: SCHERING makes no response to the allegations contained in paragraph 135 of plaintiff's Complaint which are purely of a legal nature and refers all issues of law to the Court. To the extent an answer is required, the allegations of paragraph 135 are denied as alleged, except SCHERING admits that all parties request a jury trial.

**AS AND FOR AN ANSWER TO  
PLAINTIFF'S DAMAGES**

ONE HUNDRED THIRTY-SIXTH: The allegations and all subparts of paragraph 136 are denied.



ONE HUNDRED THIRTY-SEVENTH: SCHERING makes no response to the allegations contained in paragraph 137 of plaintiff's Complaint which are purely of a legal nature and refers all issues of law to the Court. To the extent an answer is required, the allegations of paragraph 137 are denied as alleged, except SCHERING admits that all parties request a jury trial.

**AS AND FOR A FIRST AFFIRMATIVE DEFENSE**

That one or more of the causes of action are time barred pursuant to the applicable Statute of Limitations.

**AS AND FOR A SECOND AFFIRMATIVE DEFENSE**

SCHERING specifically pleads estoppel, waiver, ratification, laches, accord and satisfaction, and failure to mitigate or minimize damages, if any.

**AS AND FOR A THIRD AFFIRMATIVE DEFENSE**

Any alleged negligent or culpable conduct of SCHERING, none being admitted, was so insubstantial as to be insufficient to be a proximate or substantial contributing cause of plaintiff's alleged injuries.

**AS AND FOR A FOURTH AFFIRMATIVE DEFENSE**

Plaintiff's claims are barred, in whole or in part, because Tequin® (Gatifloxacin) was designed, manufactured, marketed, and labeled with proper warnings, information, cautions, and instructions, in accordance with the state of the art and the state of scientific and technological knowledge. SCHERING invokes all state of the art defenses applicable to plaintiff's claims, including the state of the art applicable to the industry in question, medicine, medical science, and all others, alleging that they discharged, according to law and due care, each and every duty which plaintiff may have been owed.

**AS AND FOR A FIFTH AFFIRMATIVE DEFENSE**

That any injuries which plaintiff may have sustained at the time and place set forth in the complaint herein and which resulted in his injuries therein alleged were caused in whole or in part by the contributory negligence and/or culpable conduct of the plaintiff and not as a result of any contributory negligence and/or culpable conduct on the part of SCHERING.

**AS AND FOR A SIXTH AFFIRMATIVE DEFENSE**

Plaintiff's claims are barred, in whole or in part, by the doctrine(s) contained in Restatement (Second) of Torts § 402A, Comment k.

**AS AND FOR A SEVENTH AFFIRMATIVE DEFENSE**

To the extent that plaintiff alleges that SCHERING failed to warn of known or knowable risks inherent in the use of its product, such claims are governed by the learned intermediary or informed intermediary rule or doctrine.

**AS AND FOR AN EIGHTH AFFIRMATIVE DEFENSE**

Plaintiff's claims are barred, in whole or in part, because plaintiff's injuries, if any, were the result of conduct of plaintiff, independent third parties over which SCHERING had no control, or events that were extraordinary under the circumstances, not foreseeable in the normal course of events, and/or independent, intervening, and superseding causes of the alleged injuries, including, but not limited to plaintiff's pre-existing medical conditions.

**AS AND FOR A NINTH AFFIRMATIVE DEFENSE**

Plaintiff's claims of product defect are, or may be barred by Section 4 of the Restatement (Third) of Torts: Products Liability because the product at issue complied with applicable product safety statutes and administrative regulations.

**AS AND FOR A TENTH AFFIRMATIVE DEFENSE**

Plaintiff's claims are barred, in whole or in part, because SCHERING complied with all federal and state statutes as well as all administrative regulations.

**AS AND FOR AN ELEVENTH AFFIRMATIVE DEFENSE**

Plaintiff's claims are barred, in whole or in part, because Tequin® (Gatifloxacin) is comprehensively regulated by the United States Food and Drug Administration pursuant to the Federal Food, Drug & Cosmetic Act, 21 U.S.C. § 301 et seq., and regulations and orders promulgated thereunder. Accordingly, plaintiff's claims are preempted by the Supremacy Clause of the United States Constitution, Article VI, clause 2, and the laws of the United States.

**AS AND FOR A TWELFTH AFFIRMATIVE DEFENSE**

SCHERING has no legal relationship or privity with plaintiff and owes no duty to plaintiff by which liability could be attributed to SCHERING as it relates to the attempted causes of action for breach of any warranties.

**AS AND FOR A THIRTEENTH AFFIRMATIVE DEFENSE**

SCHERING has made no warranties of any kind, express or implied, or any representations of any nature whatsoever to plaintiff. If any such warranties were made, whether express or implied, which SCHERING specifically denies, such claims are barred due to lack of privity with SCHERING, and/or for failure of plaintiff to give timely notice of any alleged breach of warranty, and by reason of disclaimers.

**AS AND FOR A FOURTEENTH AFFIRMATIVE DEFENSE**

Plaintiff's claims are barred because the use of Tequin® (Gatifloxacin) was generally recognized as safe and effective pursuant to conditions established by the Food and Drug Administration and applicable regulations, including packaging and labeling regulations.

**AS AND FOR A FIFTEENTH AFFIRMATIVE DEFENSE**

Tequin® (Gatifloxacin) was, and is, safe for its intended use and was, and is, not defective or unreasonably dangerous.

**AS AND FOR A SIXTEENTH AFFIRMATIVE DEFENSE**

The conduct of SCHERING in all activities with respect to the subject product has been and is under the supervision of the Food and Drug Administration. Accordingly, this action is barred by the Doctrine of Primary Jurisdiction.

**AS AND FOR A SEVENTEENTH AFFIRMATIVE DEFENSE**

Although SCHERING denies that plaintiff is entitled to judgment in any amount against them, SCHERING would show that any judgment against it is limited to the applicable amount or percentage of its liability.

**AS AND FOR AN EIGHTEENTH AFFIRMATIVE DEFENSE**

SCHERING is not liable for any injuries or damages plaintiff may have incurred as a consequence of any use of the product at issue which was not specifically authorized in written information accompanying its products in accordance with applicable law.

**AS AND FOR A NINETEENTH AFFIRMATIVE DEFENSE**

SCHERING hereby gives notice that, to the extent the sophisticated purchaser doctrine is applicable to any of the allegations contained in the complaint, SCHERING intends to rely upon the same in defense of this action.

**AS AND FOR A TWENTIETH AFFIRMATIVE DEFENSE**

SCHERING hereby specifically denies each and every allegation contained in the complaint by which liability is sought to be imposed upon SCHERING and gives notice that SCHERING intends to rely upon such other affirmative defenses as may become available or

known to it during the course of disclosure and discovery, and SCHERING reserves the right to amend this answer to assert any such defenses.

**AS AND FOR A TWENTY-FIRST AFFIRMATIVE DEFENSE**

Plaintiff's claims are barred by Section 6(c) and (d) of the Restatement (Third) of Torts: Products Liability. Reasonable physicians knowing of the reasonably foreseeable risks and therapeutic benefits associated with the product at issue would have prescribed and did prescribe the product for classes of patients.

**AS AND FOR A TWENTY-SECOND AFFIRMATIVE DEFENSE**

The injuries and/or damages of plaintiff (if any) were the result of unavoidable circumstances that could not have been prevented by anyone.

**AS AND FOR A TWENTY-THIRD AFFIRMATIVE DEFENSE**

Plaintiff's complaint fails to state a claim against SCHERING upon which relief can be granted.

**AS AND FOR A TWENTY-FOURTH AFFIRMATIVE DEFENSE**

The public interest and benefit and the availability of such product that is the subject matter of this action preclude liability for risks, if any, resulting from such activities, which were unavoidable given the state of human knowledge at the time those activities were undertaken. With respect to plaintiff's claims, if it is determined that there is a risk inherent in any said product, then such risk is outweighed by the benefits of the product.

**AS AND FOR A TWENTY-FIFTH AFFIRMATIVE DEFENSE**

If plaintiff suffered injuries and damages by reason of operation of nature or idiosyncratic and/or allergic reaction to the product at issue, used either alone or in combination with any other drug, SCHERING is not liable.

**AS AND FOR A TWENTY-SIXTH AFFIRMATIVE DEFENSE**

If plaintiff sustained injuries or incurred expenses as alleged, such injuries or expenses resulted from pre-existing or unrelated medical, genetic or environmental conditions, diseases or illnesses of the plaintiff that were unrelated to any of the conduct of defendant SCHERING.

**AS AND FOR A TWENTY-SEVENTH AFFIRMATIVE DEFENSE**

Any verdict or judgment rendered against SCHERING must be reduced by those amounts which have been, or will, with reasonable certainty, replace or indemnify plaintiff, in whole or in part, for any past or future claimed economic loss, from any collateral source such as insurance, social security, worker's compensation, or employee benefit programs.

**AS AND FOR A TWENTY-EIGHTH AFFIRMATIVE DEFENSE**

Upon information and belief, plaintiff had full knowledge of the risks and possible adverse effects pertaining to ingestion and use of the alleged product, and part or all of the injuries, damages, and/or losses (if any) sustained by plaintiff arose from and were caused by such risks of which he was aware, and such risks were accepted and assumed by the plaintiff, and for that reason plaintiff's recovery (if any) should be diminished, reduced, offset or barred in accordance with the principles of assumption of risk and/or informed consent.

**AS AND FOR A TWENTY-NINTH AFFIRMATIVE DEFENSE**

The product at issue was only available through the prescription of licensed physicians who were provided complete and adequate warnings and instructions consistent with the state of medical and scientific knowledge at the time.

**AS AND FOR A THIRTIETH AFFIRMATIVE DEFENSE**

Part of the damages alleged by plaintiff arising out of plaintiff's injuries is due to plaintiff's failure to mitigate his damages as required by law and therefore, may not be recovered by plaintiff in this action.

**AS AND FOR A THIRTY-FIRST AFFIRMATIVE DEFENSE**

The product of which plaintiff complains has certain unavoidable, inherent characteristics that cannot be obviated under the state of scientific knowledge existing at the time such product was manufactured. While denying that such characteristics are dangerous or defective as a matter of law, if plaintiff sustained any injuries as a result of using or exposure to this product at issue, those injuries were the result of properties necessarily associated with the product that were unavoidable and for which SCHERING cannot be held responsible.

**AS AND FOR A THIRTY-SECOND AFFIRMATIVE DEFENSE**

To the extent plaintiff is seeking recovery for benefits entitled to be received or actually received from any other source for injuries alleged in the Complaint, such benefits are not recoverable in this action.

**AS AND FOR A THIRTY-THIRD AFFIRMATIVE DEFENSE**

There is no basis for asserting independent liability against Schering Corporation. Accordingly, the Complaint against Schering Corporation should be dismissed.

**AS AND FOR A THIRTY-FOURTH AFFIRMATIVE DEFENSE**

Contingent upon the completion of discovery and to the extent applicable, SCHERING reserves the right to file such additional defenses as may be appropriate.

**AS AND FOR A THIRTY-FIFTH AFFIRMATIVE DEFENSE**

Venue is improper, or, alternatively, more convenient in another forum.

**WHEREFORE**, Defendant Schering Corporation, demands judgment dismissing plaintiff's complaint and all cross-claims with prejudice, with its costs, disbursements, attorneys' fees, and for such other and further relief as to this Court may seem just and proper.

**JURY DEMAND**

Defendant demands a trial by jury as to all issues so triable.

Dated: New York, New York  
September 25, 2007

Respectfully Submitted,

SEDGWICK, DETERT, MORAN, & ARNOLD LLP

By: 

MATTHEW J. McCAULEY (MM-9610)

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[SDMA File No. 0196-005953]

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